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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/933,106 | 08/20/2001 | Wai C. Wong | 45990-ZAA/JPW/ADM | 7129 |

7590 08/08/2002

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/08/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/933,106 | WONG ET AL. |
| | Examiner Venkataraman Balasubramanian | Art Unit 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 May 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,4,7,8,10-14,21,22,24,25,27 and 28 is/are pending in the application.

4a) Of the above claim(s) 8 and 13 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 3-4, 7, 10-12, 14, 21-22, 24-25,27 and 28 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicant's election with traverse of Group II in Paper No. 4 is acknowledged. Applicants' amendment to claims to exclude non-elected Groups I, V-VII and addition of new claims 27-28, is also acknowledged.

Claims 1, 3-4, 7-8, 10-14, 21-22, 24-25 and 27-28 are pending. Claims 8 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group V-VII.

Claims 1, 3-4, 7, 10-12, 14, 21-22, 24-25 and will be examined to the extent they embrace the elected Group II.

The traversal is on the ground(s) that a) the Group II, X= CR₇, Y= NR₆ and m+n = 2 or 3, is not independent of non-elected Groups III and IV wherein X= CR₇, Y= O or S and m+n = 2 or 3 and b) the search would not be a serious burden. This is not found persuasive for the following reasons.

Contrary to applicants' above urging that Group II, III and IV are not independent, the inventions of the Group II, III, and IV are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common structural core based on the definition of X, Y, and m+n values. Consequently, the groups have different classifications and require separate prior art searches. Prior art does not recognize them as equivalent cores and hence there is serious search burden given the fact that only limited time available to the examiner per case for examination.

Furthermore, they can be made and used independently. Art, which may render obvious or anticipate one of the groups would not necessarily do the same for the other

group. Each can support a patent, as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

However, should applicant insist on the ground that these invention as relates to the core are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the core group to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. See prior art applied below.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 7, 10-12, 14, 21-22, 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Claims 1, 22 and 25 recite the term "each" in R₇ definition which indefinite as there is only one R₇ group in the compound of formula I. Its deletion is suggested.
2. Recitation of the term "comprises" in claim 3 and 4, renders these claims indefinite the transitional phrase 'comprises" is open-ended and can include more

than what is being positively recited therein. See MPEP 2111.03 which states: The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495,501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Furthermore, claims 3 and 4 recite the limitation enationmers in line 2. There is insufficient antecedent basis for this limitation in the claim 1 on which claims 3 and 4 are dependent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 7, 21-22 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapleo et al. J. Med. Chem. 33, 1627-1630, 1989.

Chapleo et al. teaches heteroaromatic analogues of the α_2 -adrenoreceptor partial agonist clonidine, which includes compounds claimed herein. See compound 15 and 16 shown on scheme 1 page 1627, on Table 1, treating data on Table II on page 1628, experimental details on page 1630 for making these compounds.

Claims 1, 3-4, 7, 11-12, 14, 21-22 and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Henry et al. US 6,162,818.

Henry et al. teaches several 2-imidazolinylaminoindole compounds useful as α_2 -adrenoreceptor agonists for treating various disorders of α_2 -adrenoreceptors, which include compounds claimed in the instant claims. See formula I on col. 3 and note the definition of R¹, R², R³, R⁴, R⁵, R⁶, and R⁷ (note R¹ is mislabeled as R⁸ but both abstract and the tables showing compounds made clearly shows R¹). Particularly note only one of R⁴, R⁵, and R⁶ can be 2-imidazolinylamino group. See col. 7-12 for the process of making and col. 12 through col. 22 for examples. Especially see examples 193-250, 251-310, and 377-438 on col. 25 through 29, which includes compounds claimed in the instant claims for the same use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapleo et al. J. Med. Chem. 33, 1627-1630, 1989.

Teachings of Chapleo et al. as discussed in the above 102 rejection is incorporated herein.

While said compounds 15 and 16 don't anticipate the scope of claims 27 and 28 they are very closely related, being positional isomers of indole compounds i.e. 2-imidazolinylamino group in 4 position of the phenyl ring vs. 2-imidazolinylamino group in the 3-position of the phenyl ring. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Crounse*, 150 USPQ 554; *In re Norris* 84 USPQ 458; *In re Finely* 81 USPQ 383 and 387; *Ex parte Engelhardt*, 208 USPQ 343; *Ex parte Henkel*, 130 USPQ 474, regarding positional isomers. Thus it would have been obvious to one skilled in the art at the time of the

invention was made would be motivated to make these positional isomeric compounds as he would expect these compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1, 3-4, 7, 10-12, 14, 21-22 and 24-25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henry et al. US 6,162,818.

Teachings of Henry et al as discussed in the above 103 rejection is incorporated herein. As noted above Henry et al. teaches several 2-imidazolinylaminoindole compounds useful as α_2 -adrenoreceptor agonists for treating various disorders of α_2 -adrenoreceptors.

Instant claims differs from the reference in recites variously substituted indole ring bearing a 2-imidazolinylamino groups in addition to those compounds anticipated by the prior art. For example instant claim 28 require an ethyl group on the indole nitrogen which not shown in the examples of the prior art compounds.

However, Henry et al. teaches equivalency of the exemplified compounds with those claimed for compound of formula I in the definition of R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , and R^7 . Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in 5-membered nitrogen hetero ring and the aryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

References cited in the Information Disclosure Statement are at present not in the case and some of the non-patent literature is not avialble. Examiner will consider them and attach duly signed PTO1449 in the next office action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

8/7/2002.